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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/796,805 11/25/91 WINTER

6 292-59

EXAMINER

NETTER, J

ART UNIT

PAPER NUMBER

1800

10

DATE MAILED: 01/26/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9/24/92 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire THREE month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 33-63 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 33-63 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11-459.

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The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 33-63 are rejected under 35 U.S.C. § 103 as being unpatentable over Mullis et al. (A), for reasons of record set forth in Paper No. 4, mailed 27 January 1992.

At page 16 of the amendment filed 24 September 1992, at the second full paragraph, Applicants present arguments directed to both the now-withdrawn rejection under 35 USC § 102(b) and the instant rejection under 35 USC § 103. Applicants argue that there would not have been motivation to have practiced the claimed invention, and no discussion of the cloning of a repertoire of sequences. However, as set forth in the previous Office Action, novelty in the starting materials and/or in the final product does not lend patentability to an art-known process of making.

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Applicant's arguments filed 24 September 1992 have been fully considered but they are not deemed to be persuasive.

Claims 38-45 and 57-63 are rejected under 35 U.S.C. § 103 as being unpatentable over Skerra et al. (R) in view of either Mullis et al. (A) or Herzog et al. (B), and in view of Kabat et al. (S), for reasons of record set forth in Paper No. 4.

At page 18, third paragraph, Applicants argue that Skerra et al. would have provided no motivation to one of ordinary skill in the art to have cloned repertoires of variable domain sequences. However, Skerra et al. was cited for its teaching of the cloning and expression in E. coli of functional portions of immunoglobulin gene. Skerra et al. was not cited to teach or suggest the entirety of the claimed invention, but to demonstrate the availability in the art of the teachings noted supra. See also In re Lemelson, 158 USPQ 275, 277 (CCPA 1968).

At the subsequent paragraph, Applicants argue that Herzog et al. would not have provided motivation to have practiced the claimed invention, but would have taught away from it. However, the motivation to have applied the teachings of Herzog et al., as set forth in the previous Office Action, would have been the known general applicability of PCR for essentially all DNA sequences. With respect to "teaching away" from the claimed invention, of these secondary references uses selective media. With respect to the proper definition of "teaching away",

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Applicants' attentions are directed to In re Braat 16 USPQ2d 1812 (CAFC 1990). In Braat it was found that an explicit teaching that the combination would not operate was required to constitute "teaching away". Such is not present in Herzog et al. See also In re Lemelson, 158 USPQ 275, 277 (CCPA 1968).

At the first full paragraph at page 19, Applicants argue that Kabat et al. does not provide motivation to have practiced the claimed invention. As supra, however, Kabat et al. was cited to demonstrate that a large compilation of constant domain DNA and protein sequences of immunoglobulins, flanking the variable domains, was known in the art.

At the subsequent paragraph, Applicants argue that the cited references "provide no grounds for their combination" in the manner of the claimed invention, and that said references "do not in any event afford a conclusion of obviousness of the present invention." It is assumed that these two assertions are arguments against the motivations set forth in the previous Office Action to have practiced the claimed invention. In the subsequent paragraph, Applicants argue that Skerra et al. only addressed an individual Fv fragment of a known sequence, and that Skerra et al. is therefore "irrelevant to the present invention as claimed." However, the invention as disclosed is drawn, ultimately, to the expression of cloned DNAs encoding fragments of immunoglobulins, in E. coli. Clearly, then, Skerra et al. is relevant to the claimed invention.

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At the second and third paragraphs at page 20, Applicants argue that neither Mullis et al. nor Herzog et al. "teach or suggest the problems solved by the present invention, for they are simply not concerned with cloning repertoires of immunoglobulin variable domain coding sequences." However, one of ordinary skill in the art would have recognized that the general teachings of either reference could have been applied to other systems, e.g., the cloning of Fv-encoding DNAs as disclosed by Skerra et al.

Applicant's arguments filed 24 September 1992 have been fully considered but they are not deemed to be persuasive.

Claims 34-37 and 46-56 are rejected under 35 U.S.C. § 103 as being unpatentable over Skerra et al. (R) in view of either Mullis et al. (A) or Herzog et al. (B), and in view of Kabat et al. (S), as applied to claims 38-45 and 57-63 above, and further in view of Schoemaker et al. (C), for reasons of record set forth in Paper No. 4.

Applicants argue, at page 21, second paragraph, that Schoemaker et al. does not suggest the claimed invention. However, the motivation to have expressed the immunoglobulin chain fragments of the method of claims 38-45 and 57-63 as

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heterochain antibodies was set forth in the previous Office Action.

Applicant's arguments filed 24 September 1992 have been fully considered but they are not deemed to be persuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Ketter whose telephone number is (703) 308-1169.



James Ketter

January 21, 1993



RICHARD A. SCHWARTZ
SUPERVISORY PATENT EXAMINER
ART UNIT 1805